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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,548	11/28/2000	Stephen R. Quake	3153/IG638US2	8333
7590 12/14/2004			EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,548

Applicant(s)

QUAKE ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-62 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 63-66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 – 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipshutz et al. (U.S. Pat. No. 6,043,080 A). Lipshutz et al. teach an apparatus comprising: a loop channel structure communicating with at least one service channel, such as a channel connecting the reaction chambers; a microvalve separating the loop channel from the service channel; and a pump associated with the loop channel. Lipshutz et al. teach that the devices of the disclosed invention may include a central pumping chamber disposed within the body, wherein the central pumping chamber is fluidly connected to each of the plurality of reaction chambers by one of a plurality of fluid passages or channels (see col. 2, lines 56 – 65; col. 27, line 64 – col. 30, line 9; figures 4A, 4B, 4C, 5A, 6A, 6B). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114). Lipshutz et al. teach the incorporation of peristaltic pumps (see col. 28, lines 18 – 30). Lipshutz et al. further teach the incorporation of a number of

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microvalves for controlling fluid flow within the device (see col. 29, lines 58 – 66). Lipshutz et al. teach the incorporation of a detection region (see col. 4, lines 11 – 41; col. 11, lines 39 – 47; col. 30, lines 24 – 29). Lipshutz et al. teach that the apparatus may comprise a polymeric or elastomeric material (see col. 15, lines 44 – 64). Lipshutz et al. further teach that the piezoelectric pumps utilized may comprise multiple membranes in series (see col. 28, lines 18 – 30). Lipshutz et al. further teach the incorporation of a transparent detection region (see col. 19, lines 15 – 24). Lipshutz et al. teach that the apparatus may comprise a polymeric or elastomeric layer adjacent to a substrate layer (see col. 15, lines 30 – 64). Lipshutz et al. teach that the elastomeric layer may be adjacent to a transparent substrate layer (see col. 15, lines 30 – 64). Lipshutz et al. teach that the apparatus may comprise different parts, layers, or substrates, wherein the apparatus inherently comprises control lines (e.g., electrical circuitry fabricated into the device) for controlling various features of the apparatus, such as pumps, valves, mixers and sensors (e.g., temperature control elements), etc. (see col. 15, lines 30 – 64; col. 25, lines 36 – 63; col. 27, lines 12 – 67 & col. 28, lines 30). Lipshutz et al. further teach the use of bonding in fabricating the apparatus (see col. 15, lines 4 – 29). Lipshutz et al. teach the use of a controllable valve structure, such as a rupture membrane (see col. 23, lines 1 – 21). Lipshutz et al. teach the incorporation of a diaphragm valve (see col. 16, lines 37 – 67). Lipshutz et al. teach the incorporation of a pressurized fluid system (see col. 21, lines 14 – 52). Lipshutz et al. teach the incorporation of a pneumatic manifold system, which may utilize a gas such as air (see col. 21, lines 21 – 52). The loop channel has a circular configuration (see figure 5A). Lipshutz et al. teach that target molecules, such as polymer sequences, are disposed on the surface of a loop

channel (see col. 2, lines 15 – 33; col. 11, lines 33 – 47). Lipshutz et al. also teach that reagents may be incorporated within the device (see col. 5, lines 1 – 21).

Regarding claims 5 – 9, 26, 27, 29, 33, 36 – 39, 41, 59 and 61, these claims recite process or intended use limitations, such as the presence of target molecules within the loop channel, for example, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ

528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 67 – 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. Lipshutz et al. do not specifically teach the number of target loops recited in each of these claims. However, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a multitude of loop channels to facilitated an increase in the diagnostic screening capacity of the apparatus of Lipshutz et al.

Allowable Subject Matter

Claims 63 – 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art neither teach or fairly suggest the incorporation within the apparatus of Lipshutz et al. a substrate comprising a microtiter plate having microtiter wells, wherein each microtiter well comprises a target molecule patterned thereon; and the microtiter plate is connected to the treatment layer so that at least a portion of the length of each loop channel is sealed by a microtiter well.

Response to Arguments

1. Regarding the rejection of claims 67 – 69 under 35 U.S.C. 102, applicant's arguments and amendments have been fully considered and are persuasive. This rejection has been withdrawn.
2. Regarding the rejection of claims 1 – 62 under 102(e) as being anticipated by Lipshutz et al., applicant's arguments, filed 9/13/2004, have been fully considered, but they are not persuasive. As discussed above, Lipshutz et al. do teach a microfluid apparatus comprising a loop channel structure with at least one service channel. The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ

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528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114). In addition, the applicant is advised that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993); *In re Barr*, 170 USPQ 330 (CCPA 1971). "The PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art." See *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). "During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow." See *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). "The PTO broadly interprets claims during examination of a patent application since the applicant may 'amend his claim to obtain protection commensurate with his actual contribution to the art.'" (quoting *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550 (CCPA 1969)). See *In re Yamamoto*, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). The applicant cannot read limitations set forth in the description into the claims for the purpose of avoiding the art. See *In re Sporck*, 155 USPQ 687 (CCPA 1967). Although the apparatus as taught by the prior art may not be what the applicant intends as their claimed invention, the claims still encompass the teachings of the prior art. Therefore, the claims still do not *exclude* the teachings of the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

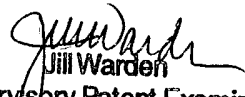
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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